

Notice of Allowability

Application No.

10/007,739

Examiner

Ginny Portner

Applicant(s)

COPELAND ET AL.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 2/26/07.
2. ☒ The allowed claim(s) is/are 2,4,7-13,16-23,25,28-35; now claims 1-26.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date <u>herewith</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |


MARK NAVARRO
PRIMARY EXAMINER

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Richard Klein on February 26, 2007.

The application has been amended as follows:

LISTING OF CLAIMS:

1. (Cancelled).
2. (Currently Amended) An anaerobic medium composition for the selective growth of anaerobes from a sample that contains at least facultative microorganisms and anaerobes, wherein said medium composition comprises a nutrient medium, a salt of an azide present in an amount of from about ~~0.04~~ 0.1 mg/ml to 1.0 mg/ml[[,]] in the medium, and oxygen scavenging membrane fragments to create an anaerobic environment, wherein the membrane fragments are derived from a respiratory system of an organism sensitive to azide.
3. (Cancelled).
4. (Previously Presented) The medium composition of claim 2, wherein the medium comprises Brain Heart Infusion, Brucella, CDC Anaerobe, Nutrient, Schaedler, Thioglycollate, or Trypticase Soy.
5. (Cancelled).

6. (Cancelled).

7. (Previously Presented) The medium composition of claim 2, wherein the sample is obtained from

- a. patients;
- b. economically important animals; or
- c. pharmaceutical, or environmental sources.

8. (Currently Amended) A method for the rapid recognition, isolation, or identification of anaerobes from a sample that contains at least facultative microorganisms and anaerobes comprising the following steps:

- a. providing a liquid medium composition comprising a nutrient medium and a salt of an azide, wherein the azide is present in an amount of from about 0.1 mg/ml to 1.0 mg/ml in the medium~~sufficient to limit the growth of facultative microorganisms while not limiting the growth of anaerobes~~, and oxygen scavenging membrane fragments to create an anaerobic environment, wherein the membrane fragments are derived from the respiratory system of an organism sensitive to azide;
- b. inoculating the sample into the liquid medium composition;
- c. incubating the inoculated liquid medium composition;
- d. determining the presence of growth in the inoculated liquid medium composition, with partial growth being indicative that an anaerobe is present; and,
- e. sampling the inoculated liquid medium composition for further characterization and isolation of the anaerobe organism.

9. (Previously Presented) A device for the transport of a sample that contains anaerobes and facultative microbes to enable the recovery of the anaerobes, wherein the device comprises the self-generating anaerobic medium composition of claim 2.

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10. (Currently Amended) A medium composition which allows for the selective growth of an anaerobe contained in a mixed sample also containing at least a facultative microbe comprising: a microbiological nutrient medium containing a hydrogen donating substance, a plurality of oxygen scavenging membrane fragments which contain an electron transport system which reduces oxygen to water in the presence of a hydrogen donor, and an inhibitor of the electron transport system required for cellular respiration, wherein the inhibitor is present in an amount of from about 0.1 mg/ml to 1.0 mg/ml in the medium~~sufficient to terminate the growth of the facultative microbes while not terminating the growth of the anaerobe~~, and wherein the oxygen scavenging membrane fragments are derived from respiring bacteria.

11. (Previously Presented) The medium composition of claim 10, wherein the hydrogen donating substance comprises an organic substrate.

12. (Previously Presented) The medium composition of claim 10, wherein the hydrogen donating substance comprises lactic acid, succinic acid, alpha-glycerol phosphate, formic acid or malic acid or any of their corresponding salts.

13. (Previously Presented) The medium composition of claim 10, wherein the oxygen scavenging membrane fragments are derived from the cytoplasmic membranes of *Escherichia coli*.

14. (Cancelled).

15. (Cancelled).

16. (Previously Presented) The medium composition of claim 10, wherein the inhibitor of the electron transport system comprises an azide or cyanide.

17. (Previously Presented) The medium composition of claim 10, wherein the inhibitor of the electron transport system comprises a salt of an azide or a cyanide.

18. (Previously Presented) The medium composition of claim 10, wherein the inhibitor of the electron transport system is sodium azide.

19. (Previously Presented) The medium composition of claim 10, wherein the microbiological nutrient medium comprises Brain Heart Infusion, Brucella, CDC Anaerobe, Nutrient, Schaedler, Thioglycollate or Trypticase Soy medium in broth or agar form.

20. (Currently Amended) A medium composition which restricts the growth of facultative microbes but not anaerobic microbes comprising a nutrient medium comprising a hydrogen donating organic substrate, one or more oxygen scavenging membrane fragments derived from the cytoplasmic membranes of bacteria, and an inhibitor of the electron transport system required for aerobic respiration in an amount of from about 0.1 mg/ml to 1.0 mg/ml in the medium.

21. (Previously Presented) The medium composition of claim 20; wherein the oxygen scavenging membrane fragments are derived from the cytoplasmic membranes of *Escherichia coli*.

22. (Previously Presented) The medium composition of claim 20, wherein the inhibitor of the electron transport system comprises a salt of azide or cyanide.

23. (Previously Presented) The medium composition of claim 20, wherein the inhibitor is sodium azide.

24. (Cancelled).

25. (Currently Amended) A medium composition which restricts the exponential growth of facultative microbes but not anaerobic microbes comprising a base medium containing a hydrogen donating substrate, oxygen scavenging membrane fragments derived from the

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cytoplasmic membranes of *Escherichia coli*, and a salt of an azide in an amount of from about 0.1 mg/ml to 1.0 mg/ml in the medium.

26. (Cancelled).

27. (Cancelled).

28. (Currently Amended) A method for the selective growth of an anaerobe from a sample containing a facultative microbe, said method comprising the steps of:

a. providing a medium composition comprising a nutrient medium containing a hydrogen donating substance, a salt of an azide in an amount of from about 0.1 mg/ml to 1.0 mg/ml in the nutrient medium, and oxygen scavenging membrane fragments which contain an electron transport system which reduces oxygen to water in the presence of a hydrogen donor, wherein the membrane fragments are derived from the respiratory system of an organism normally sensitive to azide;

b. inoculating the medium composition with the sample; and,

c. incubating the medium composition containing the sample.

29. (Currently Amended) A method for the selective growth of an anaerobe from a sample containing a facultative microbe, said method comprising the steps of:

a. providing an agar plate comprising a nutrient medium, a salt of an azide in an amount of from about 0.1 mg/ml to 1.0 mg/ml in the agar plate nutrient medium, and oxygen scavenging membrane fragments which reduce oxygen to water wherein the membrane fragments are derived from a respiratory system of an organism normally sensitive to azide;

b. providing a liquid broth comprising a nutrient medium and a salt of an azide in an amount of from about 0.1 mg/ml to 1.0 mg/ml in the liquid broth nutrient medium;

c. inoculating the liquid broth with the sample and thereafter incubating the inoculated broth;

d. inoculating the plated agar medium with the liquid broth containing the sample; and,

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e. incubating the plated agar medium inoculated with the liquid broth under anaerobic conditions thereby producing isolated colonies of the anaerobe free of facultative microbe.

30. (Previously Presented) The method of claim 29, further comprising the step of:

f. selecting isolated colonies of the anaerobes for characterization and identification.

31. (Currently Amended) A method for the selective enhancement of an anaerobe from a mixed sample also containing a facultative microorganism, said method comprising the steps of:

a. providing a liquid nutrient medium composition containing a biocatalytic oxygen reducing agent and a salt of an azide in an amount of from about 0.1 mg/ml to 1.0 mg/ml in the liquid nutrient medium compositions~~sufficient to limit the growth of facultative microorganisms while not inhibiting the growth of anaerobic microorganisms;~~

b. providing an agar plate comprising a nutrient medium, a salt of an azide in an amount of from about 0.1 mg/ml to 1.0 mg/ml in the agar plate nutrient medium, a biocatalytic oxygen reducing agent, and a hydrogen donating substance;

c. inoculating the liquid medium composition with the mixed sample and thereafter incubating the inoculated broth;

d. inoculating the agar plate with the liquid medium composition containing the mixed sample; and

e. incubating the agar plate containing the mixed sample under anaerobic conditions.

32. (Previously Presented) The method of claim 31, wherein the biocatalytic oxygen reducing agent comprises oxygen scavenging membrane fragments of bacteria normally sensitive to azide.

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33. (Previously Presented) The method of claim 31, wherein the biocatalytic oxygen reducing agent comprises oxygen scavenging membrane fragments of mitochondrial organelles.

34. (Previously Presented) The method of claim 32, wherein the bacteria is *Escherichia coli*.

35. (Previously Presented) The method of claim 31, wherein the salt of an azide is sodium azide.

36. (Cancelled).

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vgp February 26, 2007



MARK NAVARRO
PRIMARY EXAMINER